

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

CYTOLOGIX CORPORATION,

Plaintiff,

v.

VENTANA MEDICAL SYSTEMS, INC.,

Defendant.

Civil Action No. 04-11783 (RWZ)

**REPLY MEMORANDUM OF DEFENDANT VENTANA MEDICAL SYSTEMS, INC.
IN SUPPORT OF ITS CONDITIONAL MOTION TO SUPPLEMENT ITS ANSWER**

CytoLogix loses sight of the courts' repeated admonition that leave to supplement must be granted with "liberality." Instead, it offers a novel and unsupportable theory of futility in an effort to avoid responsibility for its inequitable conduct. Such a theory cannot overcome the strong federal policy reflected in the purpose of Rule 15: "to facilitate a proper decision on the merits." *Cornwall v. U.S. Constr. Mfg., Inc.*, 800 F.2d 250, 252 (Fed. Cir. 1986) (citation omitted).

I. LEAVE TO SUPPLEMENT MUST BE GRANTED WITH LIBERALITY

"Liberality is the rule in permitting supplemental pleadings." *Structural Sys., Inc. v. Sulfaro*, 692 F. Supp. 34, 36 (D. Mass. 1998). Although supplemental and amended pleadings are treated similarly, supplemental pleadings are normally "allowed as a matter of course" because they serve to bring an action up to date. *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 174 F. Supp. 2d 388, 395 (D. Md. 2001). It is against this backdrop that Ventana's motion must be considered.

II. VENTANA'S PROPOSED SUPPLEMENTAL ANSWER IS NOT FUTILE

A motion to amend may be denied for futility “only if it appears beyond doubt that the [movant] can prove no set of facts in support of her claim which would entitle her to relief.” *Spalding v. Reliance Standard Life Ins. Co.*, 835 F. Supp. 23, 31 (D. Mass. 1993) (citations and brackets omitted). CytoLogix’s futility argument does not come close to meeting this exacting test.¹

CytoLogix proposes a bright-line rule that a patent remains enforceable so long as wrongdoing in a related patent application postdates its issuance – no matter how directly

¹ In a footnote, CytoLogix attempts to argue the merits of Ventana’s inequitable conduct defense. *See* Plaintiff’s Opposition to Defendant’s Motion to Supplement Its Answer to the First Amended Complaint, at 1-2 n.1 (May 9, 2007) (Docket No. 87) (“Opp’n Br.”). This, of course, cannot provide a basis to deny Ventana’s motion, since on a motion to supplement the pleadings, all averments of the supplemental pleading must be taken as true. *McHenry v. Ford Motor Co.*, 269 F.2d 18, 24 (6th Cir. 1959).

In any event, CytoLogix’s excuse for its inequitable conduct falls far short. First, even if CytoLogix could prove that the testimony of its own expert was inaccessible to everyone who was substantively involved in prosecution of the patents, there remains no explanation for why the inventors and the patent attorney made representations to the Patent Office that were contrary to their own statements elsewhere. *See, e.g.*, Supplemental Answer to the First Amended Complaint and Counterclaim ¶¶ 29, 32-35, 43-45, 49 (lodged with the Court on April 26, 2007) (“Suppl. Answer”); Declaration of Roger J. Chin in Support of Ventana’s Conditional Motion to Supplement Its Answer, Ex. E at 116-17 & Ex. G at 8:33-37 (Apr. 26, 2007) (Docket No. 86) (“Chin Decl.”). And even if the inventors and the patent attorney could devise some explanation for these contradictions, it was incumbent upon them to provide both sides of the story to the Patent Office. “Close cases should be resolved by disclosure, not unilaterally by the applicant.” *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992).

Second, as the Court is aware, CytoLogix’s inventor, Dr. Bogen, also served as an expert in the Prior Ventana Litigation (Case Nos. 00-cv-12231 and 01-cv-10178) where his fellow expert, Dr. Slocum, contradicted statements that Dr. Bogen and CytoLogix made to the Patent Office. (Suppl. Answer ¶ 29.) Given the overlap in subject matter to which Dr. Bogen and Dr. Slocum testified in the Prior Ventana Litigation, it is difficult to believe that Dr. Bogen was unaware of the substance of Dr. Slocum’s testimony on this point. Moreover, assuming that Dr. Slocum testified truthfully, his testimony still draws into question the veracity of Dr. Bogen’s contrary statements to the Patent Office.

relevant and egregious the fraud. On this basis, CytoLogix argues that Ventana's inequitable conduct defense is futile. CytoLogix's argument is both inapplicable and incorrect. It is inapplicable because Ventana has identified inequitable conduct that occurred during prosecution of the patents-in-suit (and not just the related '693 patent), before their issuance. It is incorrect because equitable principles underlying the inequitable conduct defense do not recognize CytoLogix's proposed bright-line rule.

A. Inequitable Conduct Occurred During Prosecution of the Patents-In-Suit

The premise of CytoLogix's futility argument is that the alleged inequitable conduct occurred *only* in the '693 patent reexamination, after the issuance of the patents-in-suit ('261 and '733 patents). (Opp'n Br. at 3.) While Ventana does allege unenforceability due to inequitable conduct in the '693 patent reexamination, that is not the only basis for Ventana's defense. CytoLogix also committed inequitable conduct during prosecution of the patents-in-suit themselves.

As alleged in the supplemental answer,² CytoLogix made misrepresentations to the Patent Office on January 10, 2002, September 3, 2002, September 12, 2002, and October 4, 2002, all during prosecution of the '261 patent. (Suppl. Answer ¶¶ 69-71.) Each of these misrepresentations was made prior to issuance of the '261 patent on April 1, 2003. Likewise, during prosecution of both patents-in-suit and prior to their issuance, CytoLogix withheld highly

² On a motion to supplement a pleading under Rule 15(d), "[t]he facts alleged must be taken as true." *McHenry*, 269 F.2d at 24.

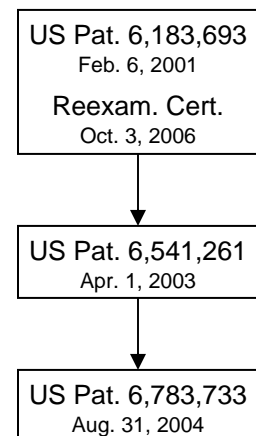
material information relating to various issues (the ‘114 patent, ISH staining, special stains) directly relevant to patentability.³ (*Id.* ¶¶ 72 & 82.)

CytoLogix bases its futility argument on a misreading of the supplemental answer. CytoLogix is mistaken when it asserts that “the patents-in-suit issued *before* the alleged inequitable conduct occurred.” (Opp’n Br. at 3.) In fact, as outlined above, the supplemental answer identifies misrepresentations and omissions that occurred both before *and* after the patents-in-suit issued.

B. There Is No Rule That Inequitable Conduct Renders Only Subsequent Patents Unenforceable

Ventana also alleges unenforceability of the patents-in-suit based on inequitable conduct that occurred during the course of the ‘693 patent reexamination. The patents-in-suit issued in 2003 and 2004, from the child and grandchild applications of the ‘693 patent, respectively.

(Suppl. Answer ¶¶ 62 & 77.) The relationship of the three patents is shown on the right. The reexamination proceedings for the ‘693 patent took place after the patents-in-suit issued. As set forth in the supplemental answer, CytoLogix committed inequitable conduct during the ‘693 patent reexamination by making material misrepresentations and concealing contradictory admissions, thereby rendering the closely related ‘261 and ‘733 patents unenforceable.



³ Although certain documents from the ‘693 patent reexamination that provide *evidence* of the misleading nature of CytoLogix’s statements did not exist until after the patents-in-suit issued (*see, e.g.*, Suppl. Answer ¶¶ 23-25, 38-40, 53-54), the information discussed in that evidence, which was withheld from the Patent Office, existed well prior to issuance of the patents-in-suit (*see, e.g., id.* ¶¶ 29, 32-35, 43-44, 47, 49, 55-56).

Inequitable conduct in connection with one patent will render related patents unenforceable when it has an “immediate and necessary relation” to enforcement of the related patents.⁴ *Consol. Aluminum Corp. v. Foseco Int’l Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990). The immediate and necessary relation of CytoLogix’s inequitable conduct to the patents-in-suit is set forth in detail in the supplemental answer. (*See, e.g.*, Suppl. Answer ¶¶ 60-84.)

CytoLogix nevertheless attempts to avoid the consequences of its inequitable conduct by asserting that the patents-in-suit cannot be tainted by the inequitable conduct that occurred after they issued. (Opp’n Br. at 3-4.) This argument is flawed for the following reasons.

First, inequitable conduct is an equitable defense, and equity is not confined by the type of bright-line rule that CytoLogix proposes. It is “not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.” *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245-46 (1933). Indeed, “[a]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim” that he who comes into equity must come with clean hands. *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945).

⁴ This is sometimes referred to as “infectious unenforceability.” *See Snaptrack, Inc. v. Zoltar Satellite Alarm Sys., Inc.*, No. C 01-20291 JW, 2006 WL 1889936, at *6 (N.D. Cal. July 10, 2006) (“Infectious unenforceability operates to bar enforcement of a patent based on inequitable conduct as to a closely related patent. To prove infectious unenforceability, an accused infringer must establish: (1) that a patent is unenforceable due to inequitable conduct, and (2) that related patents bear an immediate and necessary relation to that alleged inequitable conduct.”).

Second, the very Supreme Court case that provides the legal basis for infectious unenforceability⁵ held patents unenforceable for wrongful acts that occurred *after* they issued. In *Keystone Driller*, the five patents-in-suit were found unenforceable due to the patentee's payment to a prior inventor made to secure his agreement to falsely claim that his prior work had been abandoned and, therefore, did not qualify as prior art. 290 U.S. at 243-44. This wrongdoing occurred in 1925 – after two of the patents-in-suit already had issued.⁶

The two cases relied upon by CytoLogix provide no support for its proposed bright-line rule. *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369 (Fed. Cir. 2005), did not even concern the issue of infectious unenforceability. The issue was not raised on appeal and, therefore, was not reached. *Id.* at 1374. Instead, the defendant relied solely on the existence of a terminal disclaimer to assert that inequitable conduct in one patent taints another patent. Thus, *Pharmacia* stands for the unremarkable proposition that two patents remain separate notwithstanding the existence of a terminal disclaimer (whereby a patentee agrees that both patents will expire on the same date). *Id.* By contrast, in the present case Ventana does not solely rely on a terminal disclaimer; rather, the supplemental answer pleads facts that establish an “immediate and necessary relation” between CytoLogix's inequitable conduct in the ‘693 patent reexamination and the patents-in-suit. (*See, e.g.*, Suppl. Answer ¶¶ 28, 30-31, 36-37, 46-48, 50-51, 57-84.)

⁵ The Federal Circuit cited to *Keystone Driller* in articulating the test for infectious unenforceability. *Consol. Aluminum*, 910 F.2d at 810-11.

⁶ The patents issued in 1919, 1924, 1925 and 1929. 290 U.S. at 242 n.1. The Supreme Court refers the reader to the opinion of the Court of Appeals for details about the improper payment. *Id.* at 243. According to the lower court decision, that wrongdoing occurred in 1925. *Gen. Excavator Co. v. Keystone Driller Co.*, 62 F.2d 48, 49 (6th Cir. 1932), *aff'd*, 290 U.S. 240 (1933).

SSIH Equip. S.A. v. U.S. Int’l Trade Comm’n, 718 F.2d 365 (Fed. Cir. 1983), also does not help CytoLogix. Indeed, it disproves CytoLogix’s argument. In that case, the Federal Circuit held that the ‘762 patent was not unenforceable because the allegedly wrongful acts took place after the patent issued “**and** do not deal with the invention claimed in the ‘762 patent.” *Id.* at 378 (emphasis added). Thus, the language of *SSIH* indicates that the fact that a patent already issued, by itself, does not immunize the patent from later bad acts; the wrongdoing must **also** “not deal with the invention claimed.” *Id.* By contrast, here the alleged wrongdoing does deal with the inventions claimed in the patents-in-suit. (See, e.g., Suppl. Answer ¶¶ 28, 30-31, 36-37, 46-48, 50-51, 57-84.)

III. CYTOLOGIX FAILS TO IDENTIFY ANY OTHER FACTORS THAT FAVOR DENIAL OF VENTANA’S MOTION TO SUPPLEMENT

CytoLogix offers a laundry list of other excuses, but none justifies denying leave to supplement the answer.

First, CytoLogix complains of an undue delay. (Opp’n Br. at 6.) This is not a sufficient reason to deny Ventana’s motion. *Jones v. Bates*, 127 F.3d 839, 847 n.8 (9th Cir. 1997) (“Delay alone is insufficient to justify denial of leave to amend.”); *Tingley Sys., Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 116 (D. Mass. 2001); see also *Griffin v. County Sch. Bd. of Prince Edward County*, 377 U.S. 218, 226 (1964) (Rule 15(d) permitted supplemental pleading 10 years into litigation). Moreover, there has been no undue delay. The reexamination certificate for the ‘693 patent did not issue until October 2006 (Chin Decl., Ex. D), and Ventana filed its motion a short time later, after it became clear that CytoLogix was unable to provide any good faith explanation for its misrepresentations. (See Memorandum of Defendant Ventana Medical Systems, Inc. in Support of Its Conditional Motion to Supplement Its Answer to the

First Amended Complaint, at 8-9 (Apr. 26, 2007) (Docket No. 85).) Additionally, the Court has not imposed a discovery deadline or scheduled trial in this case. There is no undue delay.

Second, CytoLogix argues that Ventana filed its motion for an improper purpose, to take discovery for use in the Prior Ventana Litigation. (Opp'n Br. at 6-7.) This is sheer conjecture. No nefarious intentions are needed to explain the similar timing of the present motion with the motion to amend in the Prior Ventana Litigation. It is explained by the simple fact that CytoLogix's recent inequitable conduct has consequences for the closely related patents asserted in both lawsuits.⁷ In any event, CytoLogix's claim of an improper purpose puts the cart before the horse: CytoLogix can point to no allegedly improper "back-door discovery" that has occurred in this case. If it believes that any discovery is improper, CytoLogix has recourse through the normal channels. *See, e.g.*, Fed. R. Civ. P. 26(c). The inchoate fear of some future, improper discovery cannot justify denying Ventana an opportunity to litigate its inequitable conduct defense on the merits.

Finally, CytoLogix argues prejudice based on harm to the reputations of Dr. Bogen and Mr. Smith. (Opp'n Br. at 7.) Ventana is aware of no reported case in which a party has been denied the opportunity to litigate a meritorious defense in order to protect the reputations of the alleged wrongdoers. If CytoLogix wishes to protect their reputations, it can either seek to vindicate its position on the merits or dismiss its claim of infringement. Otherwise, the paramount interest before the Court should be "seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct." *Precision Instrument*, 324 U.S. at 816.

⁷ The Court may recall that this piecemeal litigation was a product of CytoLogix's decision to file a separate lawsuit in Delaware. At Ventana's insistence, this case was transferred to this Court.

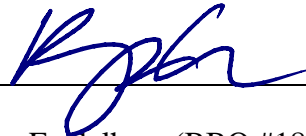
IV. CONCLUSION

For the foregoing reasons, Ventana respectfully requests that the Court grant its motion to supplement its answer to the First Amended Complaint.

Dated: May 18, 2007

VENTANA MEDICAL SYSTEMS, INC.

By its attorneys,



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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on May 18, 2007.



Roger J. Chin